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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/117,838	08/12/1998	OLEG LLIICH EPHSTEIN		4128

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EXAMINER	
OWENS JR, HOWARD V	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/117,838	EPHSTEIN, OLEG LLIICH	
	Examiner	Art Unit	
	Howard V. Owens	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-23 and 25-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-23 and 25-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

Response to Arguments

The following is in response to the amendment filed 5/2/05:

An action on the merits of claims 17-23 and 25-38 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments filed have been fully considered but they are not persuasive the rejection of claims 17-23 and 25-38 under 35 USC § 102 and 35 USC § 103 is maintained for the reasons of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-21,25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to cite that the active medicinal substance is a carrier for the potentiated medicinal substance; however, since the active medicinal substance and the potentiated medicinal substance are the same, there is no distinction between the two compounds; moreover since the potentiated dose is actually a diluted

dose of the active medicinal substance, the actual carrier is the diluent used to form the potentiated substance.

Under MPEP 2163.07, "If there are multiple definitions for a term and a definition is added to the application, it must be clear from the application as filed that applicant intended a particular definition, in order to avoid an issue of new matter and/or lack of written description". In the case of the instant claims, one of skill in the art could not clearly discern that applicant's definition of "carrier" in the amended claims is consistent with what is disclosed in the instant specification. Applicant defines a "carrier" in the specification as comprising an active medicinal substance and a potentiated medicinal substance (p. 2). Thus the active medicinal substance doesn't serve as a carrier to the potentiated medicinal substance, it is a co-component with the potentiated medicinal substance to form the "carrier". The instant specification exemplifies that the carrier is the inert material used to form the potentiated dose. For example, lactose is used to form the potentiated medicinal substance (Example 2), which is synonymous with the prior art's use of sugars to form inert carriers for the homeopathic formulation (see Amitai, col. 2, line 12).

Claim Rejections - 35 USC § 102

Claims 17 – 23, 25-28 and 36-38 are rejected under 35 U.S.C. § 102(b) as being anticipated by Amitai et al., EP 0687 466.

Claims 17 – 23 and 25-28 are drawn to a method of making a medication comprising the steps of making from an initial material an active medicinal substance in a therapeutic dose via homeopathic method.

Claim 36 is drawn to simultaneously introducing the active ingredient and a potentiated form of the active ingredient into an organism.

Claim 38 is drawn to separately introducing the active ingredient and a potentiated form of the active ingredient into an organism.

Amitai et al. anticipates the claims cited supra as it teaches the method of making a making a (columns 2-4, claims 1-3 and 7) medication via homeopathic preparation wherein an active ingredient is diluted (potentiated) with an inert carrier for administration into the human body.

Applicant's primary argument is that the prior art of Amitai does not disclose an active medicinal substance in a therapeutic dose produced from the same initial material as a potentiated medicinal substance. However, Amitai teaches that the homeopathic formulation is formed from an inert carrier (col. 1, lines 40-50). Moreover, a potentiated or diluted substance is still the same compound as the active medicinal substance and since the potentiated medicinal substance is the same as the active medicinal substance, the scope of the composition is one compound in an inert carrier.

Claim Rejections - 35 USC § 103

Claims 17-23 and 25-38 are rejected under 35 U.S.C. § 103 as being unpatentable over Amitai et al., EP 0687 466.

Claims 17 – 23 and 25-28 are drawn to a method of making a medication comprising the steps of making from an initial material an active medicinal substance in a therapeutic dose via homeopathic method. Dependent claims 29- 35 are drawn to the use of potentiated doses of known compounds.

Claims 36 and 37 are drawn to simultaneously introducing the active ingredient and a potentiated form of the active ingredient into an organism.

Claim 38 is drawn to separately introducing the active ingredient and a potentiated form of the active ingredient into an organism.

Amitai et al. teaches the method of making a making a (column 1, lines 5-27; columns 2-4; claims 1-3 and 7) medication via homeopathic preparation wherein an active or ingredient or medicament is diluted (potentiated) with an inert carrier for administration into the human body.

Amitai teaches the potentiation of any medicament and does not cite the specific compounds as claimed in claims 29-35; however, the test of the patentability of a method directed to a new use of an old compound is the unobviousness of that new use. If the result of the process is unobvious and the particular use of the material is not suggested by the prior art, the process is patentable. As such, applicant's potentiation of known compounds using the established method of homeopathic preparation as recognized by Amitai does not impart a new use nor result suggested by the prior art.

It would have been *prima facie* obvious for one of skill in the art to make a medication using potentiation or dilution of an active substance.

One of skill in the art would have been motivated to potentiate an active medicinal substance as this method has been taught in the prior art practice of homeopathic preparation for introduction of lower doses of pharmacological agents.

Applicant's primary argument is that the prior art of Amitai does not disclose an active medicinal substance in a therapeutic dose produced from the same initial material as a potentiated medicinal substance. However, Amitai teaches that the homeopathic formulation is formed from an inert carrier (col. 1, lines 40-50). Moreover, a potentiated or diluted substance is still the same compound as the active medicinal substance and since the potentiated medicinal substance is the same as the active medicinal substance, the scope of the composition is one compound in an inert carrier.

The claims have been amended to cite that the active medicinal substance is a carrier for the potentiated medicinal substance; however, since the active medicinal substance and the potentiated medicinal substance are the same, there is no distinction between the two compounds; moreover since the potentiated dose is actually a diluted dose of the active medicinal substance, the actual carrier is the diluent used to form the potentiated substance. Applicant argues that the prior art reference does not have the active medicinal substance as a carrier, however claims 17 and 18 are not drawn to the active medicinal substance as a "carrier".

Applicant defines a "carrier" in the specification as comprising an active medicinal substance and a potentiated medicinal substance. Thus the active medicinal substance doesn't serve as a carrier to the potentiated medicinal substance, it is a co-component

with the potentiated medicinal substance to form the "carrier". Applicant's argument's are also contradictory to the evidence provided in the instant specification in that lactose is used to form the potentiated medicinal substance (Example 2), which is synonymous with the prior art's use of sugars to form inert carriers for the homeopathic formulation (see Amitai, col. 2, line 12).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Howard V. Owens
Patent Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.